## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Krukonis et al.

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Title:

REDUCTION OF CONSTITUENTS IN TOBACCO

## REPLY TO FINAL OFFICE ACTION

In reply to the Final Office action that was mailed in connection with the above-captioned patent application on October 16, 2007, Applicants submit the following Remarks.

## The Office Action

Claims 1-37 are pending and stand rejected for lack of indefiniteness.

## Rejections under 35 U.S.C. § 112, second paragraph

The sole remaining ground for rejection of the present claims is indefiniteness for failure "to particularly point out and claim the subject matter which applicant regards as the invention." Specifically, the Office states: "The phrase 'under conditions' makes it unclear what parameter is particularly and distinctly being encompassed by the noted phrase. The specification provides for various parameters such as moisture, pH, pressure, and temperature, making it unclear what the phrase 'under conditions…' means." Applicants traverse this rejection.

As noted in M.P.E.P. § 2173: "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent." M.P.E.P. § 2173.02 further states:

Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A)The content of the particular application disclosure;
- (B)The teachings of the prior art; and
- (C)The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In addition, the M.P.E.P. makes it clear that "[b]readth of a claim is not to be equated with indefiniteness" (M.P.E.P. § 2173.04). Finally, "[t]here is nothing inherently wrong with defining some part of an invention in functional terms. ... A functional limitation is often used in association with ... [a] step of a process to define a particular capability or purpose that is served by the recited ... step." (M.P.E.P. § 2173.05(g); emphasis added). The present claims meet these standards.

The present claims are directed to methods of removing various constituents from tobacco using a subcritical fluid, under appropriate conditions. As noted in the previous Reply, Applicants seek patent protection for process parameters that result in the claimed effect, including appropriate combinations of moisture, pH, pressure, and temperature as exemplified in the specification. As all of the claims require use of a subcritical fluid, this limitation places absolute limits on the upper and lower temperatures and pressures that may be employed. For example, the temperature may not be so low or the pressure

so high as to solidify, i.e., freeze, the fluid. In addition, the temperature and pressure must be such that the fluid does not become supercritical. In addition, tobacco, as a plant material, will inherently possess a moisture content, and any aqueous solution will inherently have a pH. Furthermore, the specification provides ample guidance to the skilled artisan for determining such conditions, e.g., Examples 1-5. These parameters would be well understood by one skilled in the art.

As noted, the purpose of the definiteness requirement is to provide notice to the public as to the metes and bounds of the claimed invention. Claim 1 recites:

A method of reducing an amount of a constituent in tobacco, said method comprising the steps of:

- (a) providing a vessel containing said tobacco comprising said constituent;
- (b) contacting said tobacco with a subcritical fluid consisting of carbon dioxide or a hydrocarbon under conditions so that said amount of said constituent dissolves in said subcritical fluid; and
- (c) removing said subcritical fluid from said vessel, thereby reducing the amount of said constituent in said tobacco.

One skilled in the art could determine whether he or she had provided a vessel containing tobacco having the constituent. One skilled in the art could also determine whether the tobacco was contacted with carbon dioxide or a hydrocarbon under subcritical conditions. One skilled in the art would also be able to determine if the subcritical fluid had been removed from the vessel holding the tobacco. Finally, one could determine whether the tobacco had less, the same, or more of the constituent after the treatment, thereby determining whether the subcritical fluid was "under conditions so that said amount of said constituent dissolves in said subcritical fluid." Similar logic applies to the other

claims. Thus, the present claims recite a process, and one skilled in the art is capable of determining whether he or she is performing this process. Nothing more is required for definiteness.

In addition to the above, Applicants acknowledge that several conditions may be controlled during the claimed methods, such as moisture, temperature, pH, and pressure. The fact that there are many such conditions or that several variables are potentially involved is not, however, determinative on the issue of definiteness, as breadth does not equal indefiniteness.

Finally, the fact that the particular conditions are not specifically recited but rather referred to "functionally" is also not determinative. As noted above, process claims routinely use functional language to describe the capability or purpose of a step. Use of the phrase "under conditions ..." is therefore fully consistent with patent practice.

Indeed, over 28,000 patents whose claims recite the phrase "under conditions" have issued since 1976.

For all these reasons, the rejection may be withdrawn.